SUPPORTING STATEMENT
FOR
MAMMOGRAPHY FACILITIES, STANDARDS, AND LAY SUMMARIES FOR PATIENTS
21 CFR PART 900
OMB No. 0910-0309

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

The Food and Drug Administration (FDA) is requesting approval from the Office of Management and Budget (OMB) for the continuation of the information collection requirements contained in the final regulations for mammography facilities as amended. These requirements are implemented under 21 CFR Part 900 (Attachment A).

These regulations are necessary to implement the Mammography Quality Standards Act of 1992 (MQSA) (42 U.S.C. 263b) (Attachment B) as amended by the Mammography Quality Standards Reauthorization Act (MQSRA) of 1998. The MQSA requires the establishment of a Federal certification and inspection program for mammography facilities; regulations and standards for accreditation bodies for mammography facilities, and standards for mammography equipment, personnel, and practices, including quality assurance. MQSRA extended the life of the MQSA program for four years (until 2002) and also modified some of the provisions. The most significant modification required by MQSRA from a reporting and recordkeeping viewpoint under 21 CFR 900.12 (c)(2) was that mammography facilities were required to send a lay summary of each examination to the patient. The intent of these regulations is to assure safe, reliable, and accurate mammography on a nationwide level.

Under the regulations, as a first step in becoming certified, mammography facilities must become accredited by a FDA approved accreditation body. This requires undergoing a review of their clinical images and providing the accreditation body with information showing that they meet the equipment, personnel, quality assurance and quality control standards, and have a medical reporting and recordkeeping program, a medical outcomes audit program, and a consumer compliant mechanism. On the basis of this accreditation, facilities are then certified by FDA and must prominently display their certificate. These actions are taken to ensure safe, accurate, and reliable mammography on a nationwide basis.

Title 21 CFR Part 900 Mammography (Attachment A), as amended, requires:

Accreditation Body Requirements:

21 CFR 900.3 **- Reporting**
Application procedure for approval as an accreditation body.

21 CFR 900.3(b)(3) - **Reporting**
Private, non-profit organizations or State agencies are required to submit three copies of an application for approval as an accreditation body.

21 CFR 900.3(c) - **Reporting**
An approved accreditation body must apply for renewal of approval or notify FDA of its plans not to apply for renewal of approval at least nine months before the expiration date of a body's approval.

21 CFR 900.3(e) - **Reporting**
An accreditation body that decides to relinquish its accreditation authority before expiration of the body's term of approval shall submit a letter of such intent to FDA at least nine months before relinquishing such authority.

21 CFR 900.3(f)(2) - **Reporting**
An accreditation body that does not apply for renewal of accreditation, is denied such approval by FDA, or relinquishes its accreditation authority shall notify all facilities accredited or seeking accreditation by the body that the body will no longer have accreditation authority.

21 CFR 900.4(c) - **Reporting**
The accreditation body shall review clinical images from each facility accredited by the body at least once every three years.

21 CFR 900.4(d) – **Reporting**
The accreditation body shall review phantom images from each facility accredited by the body at least once every three years.

21 CFR 900.4(f) - **Reporting**
The accreditation body shall conduct onsite visits and random clinical image reviews of a sample of facilities to monitor and assess their compliance with standards established by the body for accreditation. The accreditation body shall submit annually to the FDA three copies of a summary report describing all facility assessments the body conducted under the provisions of this section for the year being reported.

21 CFR 900.4(h) - **Reporting**
The accreditation body is required to submit to FDA the information required by 42 U.S.C. 263b(d) for each facility when the facility is initially accredited and at least annually when updated. The accreditation body is required to notify FDA of applications containing information required by 42 U.S.C. 263b(c)(2) for provisional certificates and in 21 CFR 900.12(b)(2) for extension of provisional certificates. The accreditation body is required to submit to FDA the name, identifying information, and other information for any facility for which the accreditation body denies, suspends, or revokes accreditation. The accreditation

body is required to submit to FDA an annual report summarizing all serious complaints received during the previous calendar year, their resolution status, and any actions taken in response to them. The accreditation body is required to provide to FDA any other information relevant to 42 U.S.C. 263b and required by FDA about any facility accredited or undergoing accreditation by the body.

21 CFR 900.4(i)(2) - **Reporting**
At FDA's request, accreditation bodies are required to submit financial records or other material to assist FDA in assessing the reasonableness of accreditation body fees.

21 CFR 900.6(c)(1) - **Reporting**
A former accreditation body that has had its approval withdrawn may submit a new application for approval if the body can provide information to FDA to establish that the problems that were grounds for withdrawal of approval have been resolved.

21 CFR 900.3(f)(1) - **Recordkeeping**
An accreditation body that does not apply for renewal of accreditation, is denied such approval by FDA, or relinquishes its accreditation authority shall transfer facility records and other related information to a location approved by FDA.

21 CFR 900.4(g) - **Recordkeeping**
The accreditation body is required to develop and administer a written and documented system, including timeframes, for collecting and resolving serious consumer complaints that could not be resolved at a facility.

<u>General Facility Requirements:</u>

21 CFR 900.4(e) - **Reporting**
Every facility applying for accreditation is required to submit with its initial accreditation application a mammography equipment evaluation. All facilities must undergo an annual survey to assure continued compliance with accreditation standards and to provide continued oversight of facilities quality control programs as they relate to standards.

21 CFR 900.11(b)(1) **– Reporting**
A facility must apply to a FDA-approved accreditation body or to another entity as designated by FDA to qualify for a certificate for the lawful operation of a mammography facility.

21 CFR 900.11(b)(2) - **Reporting**
New facilities beginning operation after October 1, 1994 are eligible to apply for provisional certificates.

21 CFR 900.11(b)(3) - **Reporting**

A facility may apply for a 90-day extension to a provisional certificate.

21 CFR 900.11(c) **– Reporting**
A previously certified facility that has allowed its certificate to expire, that has been refused a renewal of its certificate by FDA, or that has had its certificate revoked by FDA, may apply to have the certificate reinstated.

21 CFR 900.12(c)(2) **- Reporting**
Each facility shall maintain a system to ensure that a lay summary of his or her examination is provided to each patient and that the medical report of the examination is provided to the referring physician or, in the absence of a referring physician, to the patient. These summaries and reports are to be provided within 30 days of the examination but in cases where the assessments are "suspicious" or "highly suggestive of malignancy", they should be provided as soon as possible.

21 CFR 900.12(j)(1) **- Reporting**
If FDA believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information for review by the accreditation body or other entity designated by FDA.

21 CFR 900.12(j)(2) **- Reporting**
If FDA determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patients or their designees, their physicians, or the public of action that may be taken to minimize the effects of the risk.

21 CFR 900.15(c) - **Reporting**

A facility that has been denied accreditation by an accreditation body may request reconsideration of that adverse decision by the accreditation body.

21 CFR 900.15(d)(3)(ii) **- Reporting**
A facility that has been denied accreditation following appeal to the accreditation body may request reconsideration of that adverse decision by FDA.

21 CFR 900.18(c) **- Reporting**
Mammography facilities, accreditation bodies, State governments that are not accreditation bodies, and manufacturers and assemblers of equipment used for mammography may apply for approval of an alternative standard or for an amendment or extension of the alternative standard by submitting an application to FDA.

21 CFR 900.18(e) **- Reporting**

An application for amending or extending approval of an alternative standard must provide an explanation supported by data of how such an amendment or extension would assure equal or greater quality of production, processing, or interpretation of mammograms than the original standard.

21 CFR 900.12(c)(4) **- Recordkeeping**
Facilities are required to maintain mammography films and reports in a permanent medical record of the examinee.

21 CFR 900.12(e)(13) **- Recordkeeping**
Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials.

21 CFR 900.12(f) **- Recordkeeping**
Each facility is required to establish and maintain a mammography medical outcomes audit program. As part of that program, an interpreting physician is required to review the audit data at least once every 12 months. This individual is required to identify issues and analyze results based on this audit.

21 CFR 900.12(h) **- Recordkeeping**
Each facility is required to establish a written and documented system for collecting and documenting consumer complaints and to maintain a record of each serious complaint received by the facility for at least 3 years.

Inspection Fee Exemption

Form FDA 3422 – **Reporting**

Under the MQSA, all certified mammography facilities except governmental entities, as determined by FDA, are subject to payment of inspection fees. The information provided by this form is used by FDA to determine if the facility is operated by any Federal department, State, district, territory, possession, Federally recognized Indian tribe, city, county, town, village, municipal corporation or similar political organization or subpart thereof. Collection of information from this form will also allow FDA to determine if the facility provides services under the Breast and Cervical Cancer Mortality Prevention Act of 1990.

2. By Whom and for What Purpose the Information is to be Used

This Information Collection is necessary to assure safe, accurate, and reliable mammography on a nationwide basis. Information collected from mammography facilities

has been used to ensure that the personnel, equipment, and quality systems have met and continue to meet the regulations under MQSA and will be used by patients to manage their health care properly.

Certain provisions of the MQSA require that accreditation of mammography facilities by private, nonprofit organizations or State agencies be approved by FDA according to standards established by FDA. FDA has used data from the current accreditation process to ensure that the requirements of , initially, the interim rule and, currently, the final rule are met. The information collected for accreditation bodies of mammography facilities has been and will continue to be used by FDA to ensure that private, nonprofit organization or State agencies have met the standards established by FDA for accreditation bodies to accredit facilities that provide mammography services.

3. Consideration of Information Technology

A particularly significant use of information technology in the MQSA program to reduce the reporting and recordkeeping burden is that the accreditation bodies provide the required information to FDA almost entirely by electronic means.

An example of a particularly significant use of information technology in the MQSA program to reduce the reporting and recordkeeping burden is that the accreditation bodies provide the required information to FDA almost entirely by electronic means. Most information currently is processed through the program's electronic Mammography Program Reporting and Information System (MPRIS). Presently, accreditation bodies send information electronically through the use of web pages whereby data is updated. Inspection findings are reported electronically on the inspector's laptop and then uploaded into the system. Compliance Officers and Regional Radiological Health Representatives (RRHR) modify non-compliance information found in the inspections. Billing files are created monthly and then sent electronically to a FDA contractor who then produces the bills. The MPRIS system is essentially paperless at this point, and should currently meet Government Paperwork Elimination Act (GPEA) requirements.

Other examples of reducing burden through technology includes FDA's permitting physician's electronic signatures on medical reports and its acceptance of electronic recordkeeping in such areas as the medical audit and patient reports. The use of electronic forms of reporting and recordkeeping submissions to FDA continues to remain voluntary at this point.

Any information generated for the patient's use may be communicated to the patient in any appropriate format.

4. Efforts to Identify Duplication and Similar Information Already Available

The MQSA was enacted to establish uniform national quality standards for all mammography facilities. Under the previous regulatory system, no national comprehensive mammography quality standards existed. The American College of Radiology (ACR) is the principal professional organization of physicians trained in radiology and medical radiation physics in the United States. In 1987, the ACR began the voluntary Mammography Accreditation Program (MAP), the purpose of which was to provide assurance of quality to patients seeking services at ACR-accredited facilities. Today, ACR is performing their accreditation program under FDA authority.

While some of the information previously included in the MAP was the same as now required by FDA under this Information Collection, only those facilities that had voluntarily sought accreditation previous to October 1, 1994 (less than a quarter of the total) had provided this information to the ACR. Hence, the information being collected under the MQSA has never been available for all facilities on a nationwide basis. FDA found no other information sources that were available. Because there is no similar information available to assure that mammography facilities are complying with the requirements of MQSA, the information requested under MQSA is not duplicative.

5. Impact on Small Business or Other Small Entities

FDA does not believe that the collection of information will adversely affect small businesses or other small entities. Because smaller facilities by definition have fewer employees and lower volumes of mammography examinations than large facilities, these facilities will have a lesser amount of recordkeeping and reporting burden. Thus, the amount of recordkeeping and reporting burden will be proportional to the volume of examinations at the mammography facility. Hence, facilities of all sizes will experience an equal burden in relative terms (i.e., small facilities will not be affected any more or less than large facilities).

FDA has also attempted to minimize the information collection burden on small entities by developing a small entity compliance guide. This guide was issued under section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996. Subsequently, as additional questions arose with respect to complying with the regulations, FDA has provided further guidance in answer to these questions. To date, seven major guidance documents have been made available, one of which concentrated specifically on recordkeeping questions, and others are in preparation. In accordance with Good Guidance Practices, these documents are made available electronically for public comment before they become final. As each document becomes final, the information in it is incorporated into an electronic file called the Policy Help Guidance System. This file is available to the public on the FDA's mammography Web Site www.fda/gov/cdrh/mammography, along with an incorporated search engine. Members of the public may consult the guidance on the Web Site or download it and the search engine to their own computer for more

convenient use. This guidance, like the previously published compliance guide, is intended to help small entities comply with the final regulations.

There are situations where the facilities are required to submit information of interest to both the accreditation bodies and FDA. From the beginning of the program, FDA has required only a single submission of this information. Typically the information is sent to the accreditation body, which then, as discussed above, transmits it electronically to FDA. This reduces the burden that would rise if the facility was required to submit the information directly both to FDA and the accreditation body.

Further, in the interest of maintaining flexibility while improving the overall quality of mammography, FDA has provided an avenue through which an effective alternative standard may be implemented. The Agency has created a mechanism for mammography facilities and accreditation bodies, State governments that are not accreditation bodies, and manufacturers and assemblers of equipment used for mammography to request permission to meet an alternative standard rather than an existing quality standard. The request must be supported by such evidence as required by the Agency to render a determination that the suggested alternative is at least as effective as the FDA-mandated standard in helping to achieve high quality mammography.

6. Consequences of Collecting the Information Less Frequently and Technical or Legal Obstacles

Less frequent information collection may result in an unacceptable quality of mammography being provided by many facilities. Neither the accreditation bodies nor FDA would be able to assure that facilities are adequately meeting the quality standards with less frequent information collection. FDA believes that the reporting and recordkeeping frequency in the final rule is the minimum necessary to assure safe, accurate, and reliable mammography on a nationwide basis

There are no technical or legal obstacles to the collection of this information.

7. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

This information collection is consistent with 5 CFR 1320.5(d).

8. Consultation Outside, the Agency

In accordance with 5 CFR 1320.8(d), on November 7, 2003 (68 FR 63106), a 60 day notice for public comment (Attachment C) was published in the Federal Register. No comments were received from the public.

FDA meets with its FDA's National Mammography Quality Assurance Advisory Committee (NMQAAC) twice annually. NMQAAC is made up of representatives of the mammography community, consumer groups, and government. It is charged with advising FDA's mammography program on advances in mammography technology and procedures and on appropriate quality standards for mammography facilities. NMQAAC also discusses and comments on all guidance before it is made final. The meetings are open to the public and time is allotted for public statements on issues of concern in the mammography field. The chairperson may also call upon attendees to contribute to the committee discussions.

FDA also meets or holds teleconferences several times a year with its approved accreditation bodies, which includes the American College of Radiology, to discuss issues of mutual concern. The Agency has also long enjoyed a good relationship with the Conference of State Radiation Program Directors (CRCPD), which is the professional organization of the State agencies concerned with radiation protection. The CRCPD has established a standing Mammography Committee, which meets with FDA mammography staff at least once a year.

In 2001, FDA conducted a Facility Satisfaction Survey (approved under OMB Control Number 0910-0360) to help evaluate and improve both the inspection process and communication with mammography facilities. To ensure confidentiality, an independent contractor conducted the survey and developed the final report. The survey was mailed to 1000 mammography facilities. The response rate was 74 percent. As well as asking questions, the survey included a section for write-in comments. The results of the survey are being analyzed and compared to results from a similar survey conducted in 1997 and appropriate responses to the survey findings are being initiated.

Finally, in recent years, FDA mammography staff have met several times with representatives of manufacturers working on the new applications of digital technology in mammography to resolve problems preventing the making of that technology generally available. FDA mammography staff have also worked with representatives of the manufacturers to develop quality assurance manuals for full field digital mammography units.

9. Explanation of any Payment of Gift to Respondents

No payment or gifts shall be provided to respondents under this regulation.

10. Assurance of Confidentiality Provided to Respondent

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9). FDA will make the fullest

possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information. Mammography reports and other information submitted to FDA under 21 CFR Part 900 are releasable under the FOIA as set forth in 21 CFR Part 20.

Lay summaries issued under 21 CFR 900(c)(2) will only be available to the patient or concerned health officials.

11. Justification of Sensitive Questions

This information collection does not include questions pertaining to sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimate of Hour Burden Including Annualized hourly Costs

The most likely respondents to this information collection will be accreditation bodies and mammography facilities seeking certification.

The total estimated annual reporting and recordkeeping burden for meeting the interim and final regulations is 3,219,936 hours. As explained in Section 15, this is somewhat less than originally estimated. The change is primarily due to the fact that experience gained over the past several years with the program has made it possible to formulate more accurate estimates than was possible at the time the original estimates were developed. The total hour cost estimate for the annual reporting and recordkeeping burden is estimated to be $31 million. This estimate was obtained as follows.

During the amendment of the final regulations to conform them to MQSRA, it was estimated that the new requirement to send lay summaries to all patients would increase the cost to the facilities by approximately $42.4 million in the initial year. This cost was based upon the estimated number of additional summaries to be sent, which in turn was based on the estimated number of examinations. The original estimate was based upon approximately 9800 mammography facilities performing 40 million examinations per year.

Many of these patients were already receiving lay summaries. An estimated 7.7 percent were self-referred patients, for whom lay summaries were already required. Of the remaining 92.3 percent, FDA estimated that 40 percent were already receiving lay summaries in accordance with standards of good practice. Thus additional lay summaries would have to be sent under the regulations developed to comply with MQSRA for approximately 22,150,000 examinations. It was estimated that the cost to send each lay summary was $0.95, of which $0.60 were labor costs and the remainder the cost of materials and postage. The contribution to the hour cost from this source was thus $13.3 million.

In 90 percent of these cases, the notification of the patient by such a letter is deemed sufficient. In the 10 percent of the cases in which there is a finding of "Suspicious" or "Highly suggestive of malignancy", however, the facility is also required to make reasonable attempts to ensure that the results are communicated to the patients as soon as possible. FDA believed that this requirement can be met by a 5 minute call from the health professional to the patient and estimated the cost of such a call as $8.93 dollars. For purposes of calculating hour cost, it was decided to assume that this was entirely a labor cost, although a very small part of the $8.93 would be for telephone equipment or service. Approximately 2,215,000 such calls would be made adding approximately $19.7 million to the hour cost for a total of $32.3 million.

Since the original estimate of the cost of providing lay summaries was made in 1999, the number of mammography facilities in the country has decreased. There are now approximately 9200 FDA-certified facilities. Improved data from the accreditation and certification process has also shown that that the estimated number of examinations performed annually in the country is approximately 35.1 million. For the purposes of this supporting statement, however, a figure of 36 million was used to take into account expected growth during the time period of this Information Collection. This is 90 percent of the previous estimate of the number of examinations. Using these improved figures the hour cost for sending the additional lay summaries and the additional telephone contacts would be 90 percent of the previously estimated 32.3 million or about $29.1 million.

The hour burden of sending the lay summaries constitutes approximately 94 percent of the total hour burden. The assumption was made that it also constituted 94 percent of the total hour cost estimate, thus the total hour cost estimate was approximately $31 million. FDA estimates the burden of this collection of information as follows:

Table 1. --Estimated Annual Reporting Burden

CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
900.3	1	0.33	0.33	60	20		
900.3(b)(3)	1	0.33	0.33	60	20	$50	
900.3(c)	5	0.33	1.67	15	25		
900.3(e)	1	0.1	0.1	1	0.1		
900.3(f)(2)	1	0.1	0.1	200	20		
900.4(c)&(d)	9,200	0.33	3,067	1	3,067		
900.4(e)	9,450	1	9,450	8	75,600		

CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
900.4(f)	276	1	276	7	1,932		
900.4(h)	5	1	6130	1	6,130		
900.4(i)(2)	1	0.33	0.33	1	0.33		
900.6(c)(1)	1	0.1	0.1	1	0.1		
900.11(b)(1)	9,200	0.33	3,067	2	6,134		
900.11(b)(2)	250	1	250	2	500		
900.11(b)(3)	5	1	5	.5	2.5		
900.11(c)	9,200	0.04	368	5	1,840		$1,000
900.12(c)(2)	9,200	3,478	36,000,000	5 Minutes	3,000,000		
900.12(j)(1)	25	1	25	1	25		
900.12(j)(2)	25	0.08	2	50	100		
900.15(c)	9,200	0.05	46	2	92		
900.15(d)(3)(ii)	9,200	0.0001	0.92	2	1.8		$10
900.18(c)	9,300	0.00032	3	2	6		$30
900.18(e)	10	0.0100	0.1	1	0.1		$10
FDA Form 3422	800	1	800	.25	200		
TOTAL					3,095,716	$50	$1,041

Table 2. --Estimated Annual Recordkeeping Burden

CFR Section	Number of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Operating & Maintenance Costs
900.3(f)(1)	5	0.02	0.1	200	20	
900.4(g)	1	0.33	0.33	1	0.33	

CFR Section	Number of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Operating & Maintenance Costs
900.12 (c)(4)	9,200	1	9,200	1	9,200	$18,400
900.12 (e)(13)	9,200	52	478,400	0.125	59,800	
900.12 (f)	9,200	1	9,200	5	46,000	
900.12 (h)	9,200	2	18,400	0.5	9,200	
TOTAL					124,220	$18,400

13. Estimate of the Other Total Annual Cost Burden to Respondents or Recordkeepers

A. Total Capital Cost

The total capital cost associated with these regulations is $50 (21 CFR 900.3(b)(3)). This is a one-time start up cost associated with the application for approval as an accreditation body.

B. Total Operating & Maintenance Cost

The total operating and maintenance cost associated with these requirements is: $19,441. This is the cost that facilities bear to maintain records under the initial and final mammography regulations

21 CFR 900.11(c)	$1,000
21 CFR 900.15(d)(3)(ii)	$100
21 CFR 900.18(c)	$60
21 CFR 900.18(e)	$10
21 CFR 900.12(c)(4)	$18,400

14. Annualized cost to the Federal Government

FDA is currently using 58 FTE's to implement the accreditation, quality standards, and certification provisions of the MQSA. The annual cost of these FTEs (including benefits) is 34 at $100,000 each , 22 at $84,000 each, and 2 at $87,000 each. The estimated total yearly cost is $5,420,000. Although the number of FTE's

has dropped 25 percent since the last approval of this information collection, the cost per FTE has increased about 40 per cent over the last three years. Thus, the total cost to the government since the Mammography Information Collection (0910-0309) was first approved in 1997 has increased about 8 percent.

15. Explanation for Program Changes or Adjustments

FDA had previously estimated the annual burden for reporting and recordkeeping requirements under information collection 0910-0309 to be 3,516,183 hours. However, this burden estimate was made before the implementation of the various requirements that it covered. The information available for making estimates was limited and by necessity a number of assumptions had to be made.

Since the previous estimates were made, FDA has gained several years of experience with the MQSA program and it is now possible to make more accurate estimates of the annual burden for reporting and recordkeeping. As is shown in Tables 1 and 2 the total estimated annual reporting burden from information collection 0910-0309 3,095, 716 hours and the total estimated annual recordkeeping burden is 124,220 hours for for a total of 3,219,936 hours. The use of the improved information thus allows a reduction of 296,247 hours in the reporting and recordkeeping burden when compared to the previous separate estimate for the this Information Collection.

A number of factors contributed to the reduction of hours in the improved estimates. The three most significant are:

- Only 5 accreditation bodies have applied for and received approval to date. At most, it is expected that only one additional potential accreditation body will apply for approval during the three years of the next extension of this information collection. These numbers are less than the predicted number of potential applicants and approved accreditation bodies used in the earlier estimates. In addition, the performance of the approved accreditation bodies over the past years has been on such a level that it has not been necessary to withdraw accreditation authority from any body nor has any approved accreditation body decided to relinquish its authority. It is expected that these conditions will continue. Thus the previous estimates of reporting and recordkeeping burdens related to such actions could be reduced.

- The number of mammography facilities has declined about eight percent since the earlier estimates were made. This produced a corresponding reduction in those reporting and recordkeeping burdens whose magnitudes are proportional to the number of facilities.

- The FDA estimates of the number of examinations performed annually are now based upon data the facilities themselves provided in their applications for reaccreditation. These estimates are much more firmly grounded than previous estimates that were derived from extrapolations of more limited data. The result was a ten percent reduction in the annual number of examinations from the figure used in the earlier estimates. This factor is especially significant as it impacted upon the burden of providing lay reports of examinations to patients, which is by far the largest contributor to the reporting burden (as seen from the previous estimate for Information Collection 0910-0309.)

There were some increases in the burden estimates. The largest were for:

- The recordkeeping burden for meeting 900.12(e)(13). The early estimate had focused on the estimated 6,000 facilities that had yet to establish a system for the cleaning and disinfecting mammography equipment after contact with potential infectious materials. The present estimate included 9,200 facilities as they comply with the systems that they have previously established.

- The recordkeeping burden for meeting 900.12(f). From experience it was recognized that the early estimate of one hour per recordkeeper should be increased to five hours.

However, the total of the burden increases was less than the total of burden decreases, leading to a net reduction in reporting and recordkeeping burden.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish the results of this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Not Applicable

18. Exception to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified in Item 19 of OMB Form 83-I.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

There are no statistical methods being employed in this collection of information.

List of Attachments

Attachment A	Title 21 CFR Part 900 Mammography
Attachment B	Mammography Quality Standards Act of 1992 (MQSA) (42 U.S.C. 263b)
Attachment C	Federal Register of November 7, 2003 (68 FR 63106))
Attachment D	Government Entity Declaration Form FDA-3422